

RETRODUR INTERVENTION NOTICE: OMEGA-3-ACID ETHYL-ESTERS

October 22, 2012

Dear Prescriber,

The New York State Medicaid Drug Utilization Review (DUR) Program retrospectively reviews the prescribing and dispensing of outpatient prescription medications in order to ensure that prescriptions are appropriate, medically necessary, and are not likely to result in adverse medical outcomes. At the December 2, 2011 Board Meeting, the DUR Board reviewed omega-3-acid ethyl-esters (Lovaza) utilization within the NY Medicaid program.

The National Cholesterol Education Panel Adult Treatment Panel III Guidelines¹ and European Guidelines² for hypertriglyceridemia and severe hypertriglyceridemia and the American Heart Association Scientific Statement³ were presented to the DUR Board. The National Cholesterol Education Panel Adult Treatment Panel III Guidelines¹ and European Guidelines promote fibrates and niacin as first and second line pharmacologic agents respectively, and suggest omega-3-acid ethyl-esters as adjunct or alternative treatment.

The Board recommended step therapy including trial with fibric acid derivative OR niacin prior to initiation of treatment with omega-3-acid ethyl-esters. The Board also instituted a requirement of 4 units per day in order to assist in compliance with labeled dosage requirements for treatment of hypertriglyceridemia, and asked that a provider informational letter be sent to prescribers of omega-3-acid ethyl-esters.

New York State Medicaid pharmacy claims data indicate that you have prescribed omega-3-acid ethyl-esters. Please consider this information and the clinical appropriateness of omega-3-acid ethyl-esters therapy, as the DUR Program is concerned that there may be utilization of this medication that is not consistent with current treatment guidelines and FDA-approved labeling.

In presenting this information to you, the DUR Program recognizes that safe and effective pharmacotherapy depends on the assessment of the patient's entire clinical profile. We ask that you consider the information provided regarding the prescribing of omega-3-acid ethyl-esters therapy for your patients.

Thank you for your professional assistance in this matter.

Sincerely,

John F. Naioti, Jr., R.Ph.
Manager, Drug Utilization Review Program

1. Circulation. 2002;106:3143-3421
2. Atherosclerosis. 2007;194(1):1-45.
3. Circulation. 2011;123:2292-2333